

**REMARKS**

Claims 1-54 were pending in the application. Claims 2 and 8 have been amended. Claims 1, 3-7, 9-13, 15-25, 27-31 and 33-54 have been canceled. Claims 55-65 have been added. Accordingly, upon entry of the amendments presented herein, claims 2, 8, 14, 26, 32 and 55-65 will remain pending in the application.

Claim 2 has been amended to specify that the first and second dosages of the claimed device are not both in the form of a pill, capsule or gel cap. Claim 8 has been amended to depend from claim 2.

New claims 55-65 have been added which specify that the affixing means of the claimed device comprises screw-type threads or a snap interlocking means. Support for new claims 55-65 can be found at least, for example, in Figures 5 and 6, in the description of these figures on page 12, and in the claims as originally filed. New claims 57-64 correspond to previous claims 4, 6, 14, 26, 39, 40, 43 and 44, respectively. Accordingly, no new matter has been added to the application by way of these amendments.

The foregoing claim amendments have been made solely for the purpose of expediting prosecution of the present application and should in no way be construed as acquiescence to any of the Examiner's rejections in this or in any other Office Action issued in the present application. Applicants reserve the right to pursue the subject matter of the present claims prior to being amended herein in this application or in another related application.

In view of the foregoing claim amendments and the arguments set forth below, Applicants respectfully submit that the claims are now in condition for allowance.

***Double Patenting***

The Examiner has provisionally rejected claims 1, 2, 4 and 6-12 as being unpatentable over claims 1-8 of copending Application Nos. 10/657,521 and 10/787,278. However, at this time, none of the claims in the '521, '278 or the present application have been indicated allowable. Thus,

Applicants will address the obvious-type double patenting rejection when such claims are indicated otherwise allowable.

***Claim Rejections – 35 USC § 102***

**I.)** The Examiner has rejected claims 1-12 under 35 USC § 102(b) as being anticipated by Glassman *et al.* (US 3,186,910). According to the Examiner, Glassman *et al.* “teaches a capsule comprising two or more capsular bodies connected to each other using a binder.”

Applicants respectfully disagree. However, to expedite prosecution, Applicants have amended claim 2 to specify that the first and second dosages of the claimed device *are not both* in the form of a pill, capsule or gel cap. Glassman *et al.* do not teach such a device. In fact, Glassman *et al.* teach a “novel method and pre-assembly of a pair of gelatin capsule body portions into a unitary whole” (col. 2, ll. 15-16). Thus, the medication dosages are both the same. Nor do Glassman *et al.* teach a three-dosage medication delivery device as recited in claim 8 (*e.g.*, wherein no more than two of the containment means are a pill, capsule, or gel cap). Moreover, Glassman *et al.* describe a “telescoping force” to bind the capsular bodies (col. 1, l. 69 – col. 2, l. 3). The authors do not teach or suggest the screw-type thread or snap interlocking affixing means of new claims 55-65. Thus, because Glassman *et al.* fail to teach or suggest each and every element of the claimed invention, Applicants respectfully request that the rejection under 35 USC § 102(b) be reconsidered and withdrawn.

**II.)** The Examiner has also rejected claims 1, 3, 5, 7, 9 and 11 under 35 USC § 102(b) as being anticipated by Crison *et al.* (US 5,976,571). However, Applicants respectfully note that claims 1, 3, 5, 7, 9 and 11 have been canceled without prejudice, thereby obviating this rejection.

**III.)** The Examiner has also rejected claims 1-12 under 35 USC § 102(b) as being anticipated by Aebischer *et al.* (US 5,182,111). According to the Examiner, “Aebischer discloses a delivery device comprising at least one biologically active factor encapsulated within a biocompatible membrane.”

Applicants respectfully disagree. Specifically, Aebischer *et al.* teach the delivery of active factor producing cells to a subject using “a protective, selectively permeable membrane or cell culture device, which is implanted in a target region of [the] subject” (col. 6, ll. 27-29). According to the reference, the selectively permeable containment means can be made from a variety of materials, ranging from polymers (col. 7, ll. 43-53) to hydrogels (col. 8, ll. 39-53).

Aebischer *et al.* fail to teach or suggest the use of pills, capsules or gel caps as a means of delivery of the active factor, as claimed by Applicants, let alone a combination of pills, capsules or gels. Furthermore, while this reference teaches a delivery device having “multiple cell compartments” (col. 9, ll. 48-50), these compartments are not attached by an affixing means, nor do the compartments vary in their composition (*e.g.*, as a pill-capsule, pill-gel cap or capsule-gel cap combination as claimed by the Applicants). Accordingly, because Aebischer *et al.* fail to teach or suggest each and every element of the presently claimed invention, Applicants respectfully request that the rejection under 35 USC § 102(b) thus be reconsidered and withdrawn.

### ***Claim Rejections – 35 USC § 103***

**I.)** The Examiner has rejected claims 1-54 under 35 USC § 103(a) as being unpatentable over Glassman *et al.* in view of Calanchi *et al.* (US 5,047,248) and Cody *et al.* (US 5,919,481). According to the Examiner, “Calanchi teaches [a] hard gelatin capsule [that] is transparent and neutral in color,” and “Cody teaches [a] soft gelatin capsule having translucent appearance.” The Examiner concludes that “it would have been obvious to one of ordinary skill in the art to modify the capsule of Glassman using [a] translucent and/or transparent capsule.”

Applicants respectfully traverse this rejection. As discussed above, the present claims have been amended to specify that the first and second dosages of the claimed device *are not both* in the form of a pill, capsule or gel cap. As also discussed above, Glassman *et al.* fail to teach or suggest such a device. Neither Calanchi *et al.* nor Cody *et al.* make up for this deficiency in the teachings of Glassman *et al.* Indeed, Calanchi *et al.* and Cody *et al.* merely teach transparent gelatin capsules. These references do not teach or suggest a medication delivery device made up of a combination of pills, capsules or gels, let alone one that has an affixing means in the form of screw-type threads or

snap interlocking affixing means. Thus, the presently claimed invention would not have been obvious over the combination of references cited by the Examiner. Therefore, Applicants respectfully request withdrawal of this rejection of claims 1-54 under 35 USC § 103(a).

II.) The Examiner has also rejected claims 1-12 under 35 USC § 103(a) as being unpatentable over Miller *et al.* (US 2003/0194430). According to the Examiner, Miller *et al.* disclose “a multi-component capsule comprising a primary capsule housing a secondary capsule and the secondary capsule housing a tertiary capsule.” The Examiner further states that Miller *et al.* teach a device “comprising a plurality [of] receiving chambers having an internal periphery for introducing a secondary capsule.” The Examiner concludes that “it would have been obvious to one of ordinary skill in the art to...[introduce] a tertiary capsule into one of the plurality [of] receiving chambers.”

Applicants respectfully traverse this rejection. As discussed above, the present claims have been amended to specify that the first and second dosages of the claimed device *are not both* in the form of a pill, capsule or gel cap. Miller *et al.* teach an encapsulation process for forming a multi-compartment capsule wherein a secondary capsule is positioned into a base of a primary capsule, and the primary capsule is capped. Miller *et al.* disclose that the outer walls of the capsules can be made from a variety of materials (see, *e.g.*, paragraph [0008]). However, there is no teaching, suggestion, or motivation to modify the teachings of Miller *et al.* to produce primary and secondary capsule combinations wherein the capsules are of different forms, let a three-dosage medication delivery device wherein no more than two of the containment means are a pill, capsule, or gel cap, specifically, as claimed by the Applicants.

Furthermore, the present claims are drawn to a device wherein the medication delivery means are attached by *an affixing means*. In contrast, Miller *et al.* teach a device wherein a first medication compartment is completely enclosed within a second compartment. In other embodiments described in Miller *et al.*, the second compartment completely encloses a third compartment. Thus, the device does not include an affixing means as claimed by the Applicants, nor would the use of an affixing means be obvious in view of the teachings of Miller *et al.*, let alone an affixing means comprising screw-type threads or a snap interlocking means, specifically, as claimed by the Applicants.

For at least the foregoing reasons, Applicants therefore respectfully request withdrawal of this rejection of claims 1-54 under 35 USC § 103(a) Miller *et al.*

**III.)** The Examiner also rejects claims 13-54 under 35 USC § 103(a) as being unpatentable over Miller *et al.* in view of Calanchi *et al.* and Cody *et al.* According to the Examiner, “it would have been obvious to one of ordinary skill in the art to modify the capsule of Miller using translucent and/or transparent capsule...because Miller teaches the use of gelatin capsule, and because Calanchi and Cody teaches translucent and/or transparent gelatin capsule.”

Applicants respectfully traverse this rejection. As discussed above, Miller *et al.* fail to teach or suggest the medication delivery device as claimed by the Applicants. Moreover, neither Calanchi *et al.* nor Cody *et al.*, which merely teach transparent gelatin capsules, make up for the aforementioned deficiencies in the teachings of Miller *et al.* Thus, the presently claimed invention would not have been obvious over the combination of references cited by the Examiner.

Therefore, Applicants respectfully request withdrawal of this rejection of claims 13-54 under 35 USC § 103(a).

**CONCLUSION**

In view of the foregoing, entry of the amendments and remarks herein, reconsideration and withdrawal of all rejections, and allowance of the instant application with all pending claims are respectfully solicited. If a telephone conversation with Applicants' attorney would help expedite the prosecution of the above-identified application, the Examiner is urged to call Applicants' attorney at (617) 227-7400.

An extension of time and appropriate fee is being filed herewith. If any additional fees are due, please charge our Deposit Account No. 12-0080, under Order No. AIJ-001CP from which the undersigned is authorized to draw.

Dated: March 10, 2006

Respectfully submitted,

By 

Jane E. Remillard, Esq.

Registration No. 38,872

LAHIVE & COCKFIELD, LLP

28 State Street

Boston, Massachusetts 02109

(617) 227-7400

(617) 742-4214 (Fax)

Attorney for Applicants